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ORIGINAL ARTICLE

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A prospective randomized study comparing a cervical carbon fiber cage to the Smith–Robinson technique with allograft and plating: up to 24 months follow-up

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Abstract *Introduction*: Intervertebral carbon fiber cages may reduce graft collapse and promote bony fusion. Their safety and efficacy in the cervical spine have been investigated; however, no study has compared the outcomes of anterior cervical decompression and placement of a carbon fiber cage with placement of allograft and plate. *Methods*: Forty consecutive patients who met inclusion criteria were enrolled and randomized to anterior cervical discectomy with carbon fiber cage alone ($n = 20$) or with allograft with plating ($n = 20$). Clinical and radiographic evaluations were performed at baseline and at 6 weeks, 3, 6, 12 and 24 months. Neck and arm pain as well as neck disability index (NDI) were assessed at every visit. The Short Form (SF)-36 was completed prior to operation and at 12-month intervals. Cervical radiographs were evaluated pre-op and at every follow-up for evidence of fusion and instability. *Results*: No significant difference was found between the two randomized groups with respect to pre-operative age (mean 50 years), sex, employment status, duration of pain or cervical levels affected. The mean follow-up period was 14 months (range, 6–26 months). The clinical pain and disability improvements were similar for both treatments. Post-operative donor site pain was only present in the cage group, but not of significant long-term disability. At up to 24 months, NDI scores were significantly improved in both groups when compared with baseline. At 12 and 24 months, all SF-36 questionnaire responses were also improved in both the treatment groups. However, there was no statistically significant difference in outcomes between the two groups at any time. The fusion rate was 100% in both groups by 12 and 24 months, without evidence of instability. There were no differences in complications between both groups. *Conclusions*: The outcomes after cervical decompression and placement of a carbon fiber cage appear to be similar to cervical decompression with allograft and plating by the Smith–Robinson technique.

Keywords Anterior cervical plating · Arthrodesis · Carbon fiber cage · Interbody fusion

Introduction

Symptomatic cervical disc herniation and degeneration are routinely treated by anterior decompression; however, the options for subsequent fusion and stabilization are numerous and ever increasing. The original anterior discectomy and fusion by Cloward [11] described interbody fusion with an autograft bone dowel. This was followed by the technique of Smith–Robinson describing the harvest of a rectangular tricortical iliac bone

graft for placement into the disc space with endplate preservation [23]. This general technique has only undergone minor refinements over four decades with satisfactory clinical results from many trials at about 90% [10].

Several newer interbody fusion choices are now available to the clinician. These include allograft bone and cages of a variety of materials and designs. Most grafts attempt to prevent disc space collapse, provide foraminal decompression and assist in the preservation of lordosis while promoting bony fusion [27]. Autograft is associated with not insignificant morbidity at the bone-graft donor site. This has increased the popularity of allograft. However, several studies have indicated allograft fusion rates to be inferior to autograft [5, 12, 13, 17]. Anterior instrumentation is now routinely used to potentially enhance fusion [6].

Cages have been used successfully in the lumbar spine for fusion [8, 13]. Several types of cages such as threaded screws, titanium cylinders and carbon fiber cages have been introduced for cervical spine use [2]. Carbon fiber cages are reinforced polymer implants designed to alleviate the mechanical demands on the bone fusion-promoting graft material. Carbon fiber implants are at least as stiff and elastic as cortical bone resulting in a physiologic distribution of load to the bone graft [21]. Consequently, this may stimulate bone formation and improve fusion [16, 28].

Several studies have investigated the feasibility of using carbon fiber cages in the cervical spine with autograft, allograft and hydroxyapatite graft material [1, 18, 19, 25]. Few randomized studies that compare carbon fiber cages with a standard procedure exist [22]. One prospective trial compared the outcomes of cervical carbon fiber cage placement to the Cloward procedure demonstrating no significant difference in clinical outcome save decreased donor site pain [27].

Since the need for quantified comparisons of new technologies with standard therapies is warranted, a prospective randomized study was undertaken to compare the clinical and radiological outcomes of carbon fiber cage placement with allograft and plating by the Smith–Robinson procedure in patients with symptomatic degenerative cervical spine disease.

Materials and methods

Patient population

This study was approved by the Institutional Review Board. Consecutive patients with neck pain or upper extremity radicular symptoms with or without myelopathy resulting from cervical degenerative disc disease who met certain criteria (Table 1) were evaluated for inclusion into the study. After informed consent was obtained, the patients volunteered to be included in or excluded from the study. Patients were then randomized prior to surgery to receive a carbon fiber cage or an allograft. Forty patients were enrolled in total with 20 in each treatment group. Patient characteristics are summarized in Table 2.

Instrumentation

The Cervical I/F Cage (DePuy Spine, Inc., Raynham, MA, USA) is a carbon fiber-reinforced hollow biocompatible polymer implant designed to replace the tricortical bone graft. The implant was designed to withstand physiological loads as well as having the modulus of elasticity of cortical bone. It is radiolucent, which aids in the assessment of bony fusion. Three intrinsic tantalum beads serve as radiographic markers. There are ridges to resist expulsion, and each cage has seven degrees of cant.

Surgical technique

All operations were performed by one surgeon (DHK). Patients received general inhalation anesthetic. A left-sided anterior approach to the cervical spine was performed as described by Smith and Robinson [23]. The

Table 1 Patient selection criteria used for inclusion into study

Inclusion criteria	Exclusion criteria
Age 18–70	Disc degeneration at more than two disc levels
Degenerative disc disease at one or two adjacent cervical levels: C4/5, C5/6, C6/7 (on MRI)	Prior cervical spine surgery excluding posterior laminotomy or foraminotomy
Persistent cervicalgia/radiculopathy refractory to at least 6 weeks of conservative treatment	Gross instability secondary to trauma
	Lumbar spine disability
	History of disc or spine infection
	Spine tumor
	Osteoporosis or metabolic bone disease
	Pregnancy
	Any significant illness
	Psychological disturbance

Table 2 Details of 40 patients randomized to allograft and plate or cervical carbon fiber cage

	AP patients ($n=20$)	CC patients ($n=20$)
Age	50.0 ± 9.3	48.1 ± 8.5
Male/female	11/9	11/9
Smoker	5	5
Employed	11	9
Neck pain	16	14
Radiculopathy	16	16
Myelopathy	3	4
Neck pain duration (months)	36 ± 57	17 ± 21
Arm pain duration (months)	13 ± 15	15 ± 18
One level	12	9
Two levels	8	11
C4–5	2	3
C5–6	16	14
C6–7	10	14

No statistically significant difference between the groups. Values presented as mean ± standard deviation
AP allograft and plate; *CC* carbon fiber cage

disc space was opened and distracted with Caspar posts. A discectomy was performed. The posterior longitudinal ligament was opened, and nerve roots were decompressed. A posterior osteophytectomy was performed as needed. The dura and origin of the nerve roots were visualized in all cases. Endplates were cleaned and fashioned with curettes and a high-speed pneumatic drill. For the allograft patients, a pre-sized human dense cancellous bone graft was selected and impacted into place. Anterior instrumentation with rigid plate and unicortical locking expansion screws was performed. All but one patient received a DOC^{TM} Plate (DePuy Spine, Inc., Raynham, MA, USA). One patient received a PEAK^{TM} Polyaxial Anterior Cervical Plate (DePuy Spine, Inc., Raynham, MA, USA). For the carbon fiber cage patients, a small incision (<3 cm) at the iliac crest was made and an adequate amount of cancellous bone was harvested and placed into a pre-sized cage prior to impaction. All procedures were performed in an inpatient setting. Patients were mobilized on post-op day.

Follow-up evaluation

Clinical and radiographic evaluations were performed pre-operatively and post-operatively at 6 weeks, 3, 6, 12 and 24 months. Clinical evaluations for pain and neurological function were conducted at each visit. Muscle strength and sensory exams were documented. All adverse outcomes were recorded.

Antero-posterior and lateral cervical radiographs were performed at every visit. Fusion status and radiographs were evaluated by independent observers other than the surgeon. Fusion was defined as the presence of solid bone at the bone interfaces and/or through the cage. Partial bone bridges and bone outside the cage were noted but not considered to be evidence of fusion. Flexion and extension exams were analyzed at 12 and 24 months for segmental instability (spinous process widening of >2 mm at fused levels).

Neck and arm pain were quantified on a five-point subjective scale (1, none; 2, slight; 3, mild; 4, moderate; 5, severe). Disability was quantified by the neck disability index (NDI). This score is based on responses to 10 questions addressing pain intensity, personal care, lifting, reading, headache, concentration, working, driving, sleeping and recreation. The resultant score from 0% to 100% reflects the amount of disability (100% is maximum disability). The Short Form (SF)-36 Health Status Questionnaire was used to obtain the eight subscores related to mental and physical health before surgery and at every 12-month follow-up. The subscores range from 0 to 100 with 100 being the most positive score of function. The patient's subjective perception of overall satisfaction was obtained by asking whether they would have their procedure again.

Differences were measured between groups for statistical significance by non-parametric Mann–Whitney U test and the chi-squared test. Continuous variables were compared with the *t*-test where applicable. Significance was set at 0.05. Values are given as mean ± standard deviation. Statistical tests were performed with SPSS software (SPSS, Chicago, IL, USA).

Results

No statistically significant difference with respect to age, gender, duration of arm and neck pain, employment status, smoking, the number of levels and the levels affected were found after randomization of the two groups. Of the 40 patients enrolled, 21 patients had one level treated and 19 had two levels treated. The most common operative levels were C5–6 (51%) and C6–7 (41%). The most common two-level procedure was from C5–7. There was no significant difference between the two randomized groups with respect to operative time, blood loss or hospital stay.

Follow-up was available for all patients. The mean follow-up period was 14 months (range, 6–26 months). Fifteen patients who received allograft and plate, and 16 patients who received carbon fiber cages have 12 months follow-up data. Five patients who received allograft and plate, and 6 patients who received carbon fiber cages have 24 months follow-up data.

Pain scores for both neck and arm pain significantly improved in the longitudinal analysis of scores prior to surgery with scores at 12 months after surgery ($P<0.01$). These scores did not change significantly after 12 months. The pain scores improved from 4.5 ± 0.7 pre-

op to 2.4 ± 1.3 at 12 months and 1.6 ± 1.1 at 24 months for the allograft with plate patients. The pain scores improved from 3.9 ± 1.3 pre-op to 1.8 ± 0.9 at 12 months and 1.7 ± 1.1 at 24 months for the cervical cage patients. There were no significant differences in scores between the two treatment groups prior to surgery or at any follow-up after surgery.

Clinical evaluation of the patients correlated with the pain scores, again noting no differences between the two groups. The proportion of patients whose radicular symptoms improved was not significantly different in either group, nor did these patients get worse over time. Post-operative donor site pain was present in the cervical cage group. Five cervical cage patients (20%) reported moderate to severe graft site donor site pain at 6 weeks follow-up; however at 12 months, none of these patients reported anything beyond mild discomfort. None of the patients had pain that prevented daily activities.

The mean NDI scores were similarly and significantly improved in the longitudinal analysis of scores at 12 months ($P < 0.05$). The NDI scores for patients treated with allograft and plates improved from 35.2 ± 18.2 pre-op to 18.0 ± 16.6 at 12 months and 19.6 ± 15.6 at 24 months. The NDI scores for patients treated with carbon fiber cages improved from 38.6 ± 19.6 pre-op to 15.8 ± 16.6 at 12 months and 12.4 ± 17.0 at 24 months. There were no significant differences between the two treatment groups at any follow-up time point (Fig. 1).

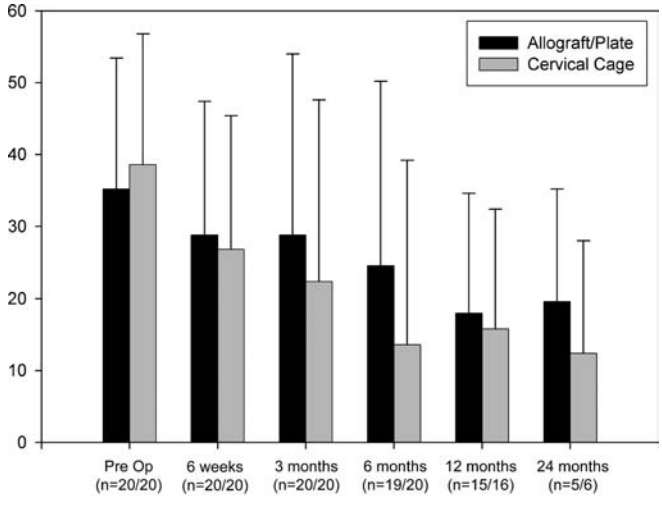

Fig. 1 Mean NDI scores for both treatment groups at pre-op and each subsequent follow-up. The *whisker* represents one standard deviation. The number of patients available for review is listed below the follow-up time as number of allograft and plate patients/cervical cage patients. No statistically significant difference is noted between both groups at any time. Both groups demonstrate statistically significant improvement of scores at both 12 and 24 months versus pre-op ($P < 0.05$). No statistically significant difference in scores is noted at 12 and 24 months in either group

General physical and mental condition information from the SF-36 Questionnaire pre-op was only significant for a difference in the general health perception of the patients between the two groups ($P < 0.05$). Otherwise, no statistically significant difference was noted in any of the scores between the two treatment groups at pre-op, 12- and 24-month follow-up. At 12 months, the role of physical (RP) disability score was nearly significantly different ($P = 0.07$) favoring the cervical cage group, but this was not seen at 24 months (Fig. 2).

The percentage of patients who reported that they would most likely or definitely have their procedure again at 6, 12 and 24 months was 70%, 82.5% and 80%, respectively, for the allograft with plate patients. Accordingly, the cervical cage patients reported 84%, 88% and 100% positive response rates at 6, 12 and 24 months, respectively.

The fusion rates of the study groups were analyzed at 6 weeks, 3, 12 and 24 months after surgery. Table 3 lists the number of levels fused versus the number of levels analyzed. More fusion had occurred in the cervical cage group at 3 months. However, there was no significant difference at the remaining time points. By 12 months, all the levels had evidence of radiographic fusion. This

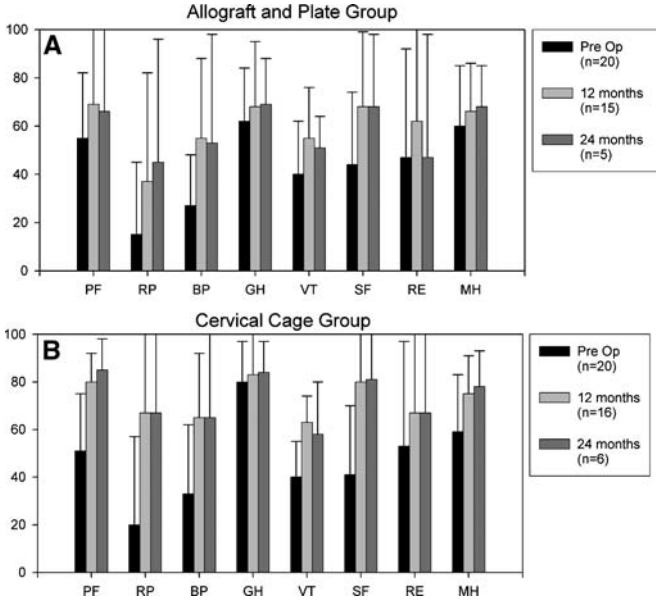

Fig. 2 Mean Short Form (SF)-36 scores for both the allograft and plate group (A) and the cervical cage group (B) at pre-op and every 12-month follow-up period. The *whisker* represents one standard deviation. The subscores are defined as follows: PF, physical functioning; RP, role of physical disability; BP, bodily pain; GH, general health; VT, vitality; SF, social functioning; RE, role of emotional disability and MH, mental health. At pre-op, no statistically significant difference is noted in scores between both groups except for GH which is significantly higher in the cervical cage group ($P < 0.05$). No statistically significant difference is noted between both groups at any follow-up

Table 3 Fusion results of 61 disc levels in 40 patients treated with allograft and plate or cervical carbon fiber cage

Follow-up	AP patients	CC patients
6 weeks	1/28 (4%)	1/31 (3%)
3 months	3/28 (11%)	9/29 (31%)
6 months	14/27 (52%)	18/29 (62%)
12 months	22/22 (100%)	24/24 (100%)
24 months	7/7 (100%)	10/10 (100%)

Number fused/number reviewed (percentage fused)
AP allograft/plate; *CC* carbon fiber cage

persisted through a 24-month follow-up. Figure 3 illustrates a typical cervical cage fusion result showing a solid fusion mass in the center of each cage connecting the inferior and superior endplates with no obvious lucent interface. No segmental instability was noted on flexion, and an extension x-ray was performed at 12 and 24 months in either treatment group.

There were no complications in the peri-operative or immediate post-operative period. Five patients reported moderate to severe exacerbation of neck and arm pain only in the first 9-month follow-up period. Three had sustained mechanical trauma; one from an altercation, one from heavy lifting, and one from strenuous exercise. The remaining two, one patient from each group, had no ascertainable inciting factor. All patients reported resolution of their exacerbations to baseline with conservative treatment consisting of medications, physiotherapy and rest. One patient had an episode of spontaneously resolving slurred speech 5 days post-op. A stroke workup was negative, and the patient recovered fully. No graft or cage dislodgements were noted. No patients required revision surgery. No evidence of tissue response or rejection of the cage was noted. One patient underwent lumbar spine surgery 9 months after cervical surgery with no complications.

Discussion

The results of this prospective randomized trial comparing the Smith–Robinson technique for anterior cervical discectomy and fusion with allograft and plate instrumentation versus with cervical carbon fiber cage placement indicate that outcomes are not significantly different with respect to pain relief, neck disability, physical and mental health, overall satisfaction and fusion at up to 24 months.

Clinical evaluation

Both treatments resulted in significant improvement in patient pain and disability when compared with their pre-operative conditions. The neck and arm pain scores were most significantly improved, but they are less statistically reliable as an outcome measure than the NDI and SF-36. The NDI scores were improved over time with the improvement stable after 12 months. Short Form-36 scores for mental and emotional components were high to begin with and had the least amount of improvement. Improvement of the physical components was more pronounced. Again, the interval improvement between 12 and 24 months was not significant. The most improvement was noted in bodily pain, social functioning and physical limitations ($P < 0.05$). It is likely that the improvement of neck and arm pain noted would increase these scores. Patients expressed

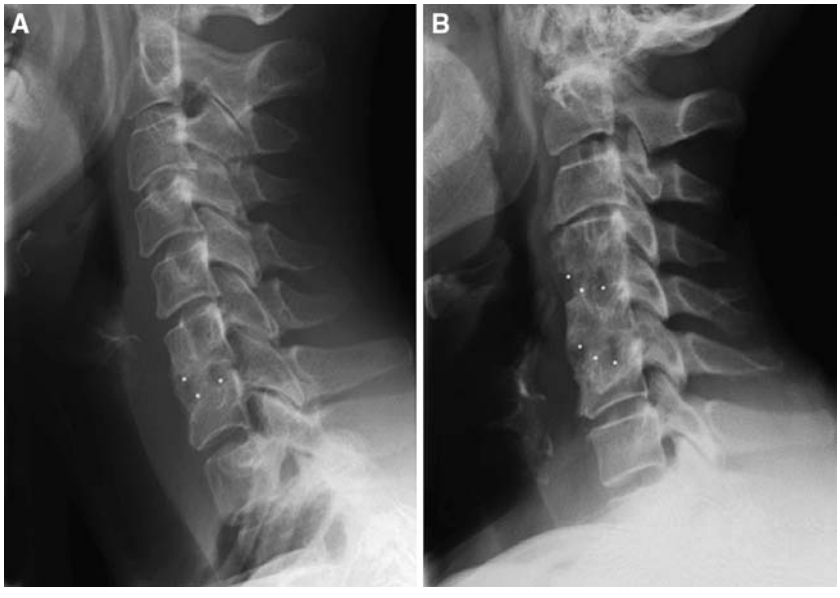

Fig. 3 (**A**) Lateral radiograph of a C6–7 cervical cage fusion at 12 months after surgery demonstrating a bridging post of bone through the cervical cage connecting the vertebral bodies. Note that the cage is radiolucent and creates no imaging artifact. The three tantalum markers note the location and orientation of the cage. (**B**) Lateral radiograph of a C4–5, C5–6 two-level cervical cage fusion at 12 months after surgery demonstrating bony fusion at both levels

high satisfaction with either procedure. The overall performance of the carbon fiber cage without instrumentation appears to be comparable with allograft fusion with plating.

These overall results are similar to the results from a prospective trial comparing the cervical carbon fiber cage with the Cloward procedure. Vavruch et al. [27] found the clinical outcome for both treatment groups was the same. Their study and the above results are also comparable with other studies reviewing anterior cervical fusion procedures reporting symptomatic relief and patient satisfaction approaching 90% [10, 22, 25].

Radiographic evaluation

Preliminary experience with cervical carbon fiber cages reported by Brooke et al. [9] reported improvement in 14 of 17 patients with neck pain and bony fusion in all 19 reviewed cases. Agrillo et al. [1] implanted 57 cages packed with coralline hydroxyapatite and reported no implant-related complications and complete fusion in all patients at 12 months. Tancredi et al. [25] also reported 119 carbon fiber cages packed with autograft, allograft or hydroxyapatite. All scans after 6 months demonstrated fusion. To avoid donor site complications altogether, empty carbon fiber osteoconductive polymer cages were placed by Payer et al. [18], who reported segmental stability in all 25 patients and bone fusion in 24. Hacker et al. [14] reported nearly 100% fusion rates with threaded carbon fiber cages and autograft versus 90% for non-instrumented bone graft alone. Salame et al. [19] reported 98% fusion in 100 patients with the I/F carbon cage. This current study supports these promising results.

However, these fusion results differ from the fusion results of a trial reporting only 62% fusion for carbon fiber cages and 86% for the Cloward procedure with mean 36-month follow-up [27]. The authors argue that the reason for this discrepancy is based on the criteria by which fusion is determined. In particular, a significant number of patients were found to have radiolucent lines through their cages and were classified as having radiographic pseudoarthrosis. However, the correlation of fusion with clinical outcome was not strong.

An advantage of the carbon fiber cages when compared with other cages is radiolucency. This provides for rapid and, theoretically, more certain assessment of bony fusion. The previous results demonstrate that interpretation may not be so straightforward. Fusion determination at the allograft to endplate interface is more readily identified than in most cages. A difficulty encountered is that cancellous bone often does not form an obvious boundary layer with the adjacent bone. A ''haze'' of bone within the cage could be mistaken for active fusion in early follow-up. However, clinical outcomes do not necessarily correlate with radiographic results. The potential confusion emphasizes that a better understanding of the manner in which bone fuses through a cage and the actual importance of radiographic fusion is necessary and cannot be answered by the currently available studies. Should pseudoarthrosis indeed be more prevalent than reported earlier, it may be worthwhile to supplement cages with anterior plating. However, only significant improvement in clinical and radiographic outcomes could justify the additional expense and potential morbidity.

Rationale for carbon fiber cages

With such similar results, the selection of the optimal graft material and fusion option will continue to be a subject of ongoing debate. Subsidence of allografts has sparked interest in using load-bearing implants such as cages. The ideal cage should correct deformity and provide stability until fusion occurs with no additional morbidity [15]. Carbon fiber reinforced polymer cages were introduced almost a decade ago for use as a spacer. They do not induce an inflammatory response [7] and have a modulus of elasticity almost equal to the cortical bone. Since the graft behaves like the cortical bone it is buttressed upon, the graft inside the implant theoretically experiences a more physiologic loading[21].

The rationale for using autograft stems from research that indicates superior fusion with autograft bone versus allograft. Floyd et al. [13] reviewed 379 cervical fusion levels and noted that autograft demonstrated a higher rate of radiographic union and a lower incidence of graft collapse. Bishop et al. [5] prospectively studied 132 patients and reported that autograft was superior to allograft for single- and multi-level fusions with respect to fusion, stability and maintenance of foraminal height.

Autograft bone graft within cages is readily integrated into a fusion mass [26]. Since the cage bears the load of the head and upper spine, no load bearing responsibility is placed on the bone-graft material. Therefore, graft material as soft as cancellous bone can be used. Cancellous bone can be obtained with less morbidity and incorporates more quickly than allograft [14]. This may account for the findings that a higher percentage of levels were found fused in the cervical cage group at 3 months, though this difference was not detectable at later follow-ups.

Autograft harvesting is associated with significant morbidity in procedures requiring extensive dissection. Severe complications, especially debilitating pain, may range from 10% to 25%, while minor complications are even more frequent (39–50%) [3, 20, 24]. Minor postoperative donor graft site morbidity was present in 20% of the patients in this study. No major morbidity has

been noted. This is likely because of the limited dissection required to obtain a small amount of cancellous bone. A previous carbon fiber cage trial also noted decreased donor site pain when compared with traditional iliac graft harvest [27]. With decreased graft site morbidity, the limited harvesting of autograft may be justified in the case of cervical cages to increase fusion rates, though in this study both groups had equal fusion rates.

Though not specifically studied here, carbon fiber cages may be more resistant to subsidence and disc space collapse. Bartels et al. [4] reported on 13 patients who had carbon fiber cages implanted and were followed with computed tomography. Bilateral neural foramina were significantly decompressed up to 1 year after placement [4]. Biomechanical evaluation suggests that hollow carbon fiber wedge cages have the highest stabilizing effect and resistance to subsidence due to its geometry versus titanium mesh cylinders and threaded cages [2, 28]. Another study of eight different cervical cage designs (not including the current spacer), however, noted that design variations may be of little importance [15].

Statistics

Statistical analysis of the data suggests that there is significant improvement in pain and functioning scores with either cage or allograft and plate treatment. However, no differences were noted between either treatment group at any time point with respect to clinical outcomes or radiographic fusion. Despite the small sample size, statistical significance for individual post-op endpoints (pain scores, NDI, SF-36) was found. However, given the negative result of the comparison between treatments, the power of the study becomes of concern. Given that power is related to the variance of the data and the sample size, this study data is limited by large variances within and small size of the sample. For instance, with a desired power of 0.80, this study can detect an eight-point NDI difference with $P < 0.05$. The certainty of not missing a subtle difference between the groups would be increased with more samples. However, hundreds of samples would be required to detect a two-point NDI difference. Our results do not indicate a difference between treatment groups at all tested endpoints. Such data are very suggestive and given the variance of the population, larger numbers are required to increase our confidence in treatment equivalency.

Conclusions

Cervical carbon fiber cages are promising in their ability to provide structural support while promoting bony fusion. Their radiolucency and biomechanical design properties make them a superior choice among available cages. The potential benefit of enhanced fusion rates and decreased bone donor site morbidity may justify the use of cancellous autograft with cages. This study demonstrates that the clinical and radiographic outcomes after cervical decompression and placement of carbon fiber cage appear to be similar to cervical decompression with allograft and plating by the Smith–Robinson technique at up to 24 months. The cost of the cage and the added operative time and morbidity of autograft should be factored against the cost of allograft and plate instrumentation in considering its use.

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